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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/683,537

10/09/2003

Todd Allen Berg

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ROPES & GRAY LLP  
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NEW YORK, NY 10036-8704

EXAMINER

SNOW, BRUCE EDWARD

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/683,537	<b>Applicant(s)</b> BERG ET AL.	
	<b>Examiner</b> Bruce E. Snow	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 108-119, 143-145 and 147-150 is/are pending in the application.
- 4a) Of the above claim(s) 115-119 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 108-114, 143 and 147-150 is/are rejected.
- 7) ☒ Claim(s) 144, 145 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/4/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed 4/4/08 have been fully considered. Applicant has amended claim 1 stating the first and second sets of fingers are unitary with the medial portion. Unitary is defined by Encarta as:

**u·ni·tar·y** [ yó·ní tē·rē ]

adjective

#### **Definition:**

- 1. relating to unit:** relating to or consisting of a unit

Regarding the Sideris rejection, it is the Examiner position that first and second sets of fingers are unitary with the medial portion as defined above. Similarly, regarding Lesh et al rejection, it is the Examiner position that first and second sets of fingers are unitary with the medial portion as defined above. The elements including 11 and 12 and 29 form a unitary unit. Same for the combination rejection of Kazuyuki et al (EP 1013227, applicant cited 11/30/07) in view of Das (5,334,217). Note the new rejection anticipated by Stevens et al (WO 96/32882, applicant cited 4/4/08).

### ***Allowable Subject Matter***

Claims 144 and 145 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 108-114, 143, 147-150 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stevens et al (WO 96/32882, applicant cited 4/4/08).

Referring to at least figure 25A, Stevens et al teaches:

108. (Currently Amended)

A device for use in closing septal defects comprising: a medial portion including elements 261, 256, 250 (tubular) having a longitudinal axis; and first and second sets of fingers 252, 260 unitary with the medial portion and capable of extending substantially radially outward from the axis, the first set of fingers unconnected to the second set of fingers at the radially outward ends and the first set of fingers being spaced an axial distance apart from the second set of fingers on the axis, and wherein only one set of fingers 260 is covered by a web of material 244 between adjacent ones of the fingers.

Claims 108-110, 112, 114, 143, are rejected under 35 U.S.C. 102(e) as being anticipated by Sideris (5,433,727). Referring to figure 3, Sideris teaches:

108. (Currently Amended)

A device for use in closing septal defects comprising: a medial portion (including elements 26) having a longitudinal axis; and first and second sets of fingers 18, 14, unitary with the medial portion and capable of extending substantially radially outward from the axis, the first set of fingers unconnected to the second set of fingers at the radially outward ends and the first set of fingers being spaced an axial distance apart from the second set of fingers on the axis, and wherein only one set of fingers 18 is covered by a web of material 16 (see figure 1) between adjacent ones of the fingers.

Regarding claim 114, see figure 3. Claim 114 is interpreted as positively claiming the device for closing septal defects.

Regarding claim 143, the device is capable of being formed from a hollow tube as a starting material which is melted down to form wire.

Claims 108-110, 112, 114, 143 are rejected under 35 U.S.C. 102(e) as being anticipated by Lesh et al (6,152,144).

Referring to at least figures 3a and 3b, Lesh et al teaches:

A device for use in closing septal defects comprising:

a medial portion 28 having a longitudinal axis; and

first and second sets of fingers unitary with the medial portion and capable of extending substantially radially outward from the axis, the first set of fingers unconnected to the second set of fingers at the radially outward ends and the first set of fingers being spaced an axial distance apart from the second set of fingers on the axis, and wherein only one set of fingers 11 is covered by a web of material between adjacent ones of the fingers.

Regarding claim 114, see figure 9.

Regarding at least claim 143, the fingers are made of wire which could have been formed from melting down the metal of a tube, sheet, anything. Note that the shaft 12 can be tubular as shown in figure 3.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 111, 113, and 147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sideris (5,433,727).

Sideris teaches the device as described above, however, fails to specifically teach nitinol. It would have been obvious to one having ordinary skill in the art have used nitinol for such a material for it's well known characteristics such as biocompatibility. Regarding silicone, Sideris teaches polyurethane; it would have been obvious to one having ordinary skill in the art have used silicone for such a material for it's well known characteristics such as biocompatibility.

Regarding claims 147-150, Sideris teaches an intra-cardiac device made of wire, but fails to teach what material the wire is made of. It would have been obvious to one skilled in the art to have made the wire of Sideris from nickel titanium alloy, stainless steel, thermoplastic, or elastic material for their known use as cardiac device including stents for their known characteristics including biocompatibility.

Claims 111, 113, and 147-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al (6,152,144).

Lesh et al teaches the device as described above, however, fails to specifically teach nitinol. It would have been obvious to one having ordinary skill in the art have

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used nitinol for such a material for it's well known characteristics such as biocompatibility. Regarding silicone, it would have been obvious to one having ordinary skill in the art have used silicone for such a material for it's well known characteristics such as biocompatibility.

Regarding claims 147-150, it would have been obvious to one skilled in the art to have made the wire of Sideris from nickel titanium alloy, stainless steel, thermoplastic, or elastic material for their known use as cardiac device including stents for their known characteristics including biocompatibility.

Claims 108-114, 143, 146-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kazuyuki et al (EP 1013227, applicant cited 11/30/07) in view of Das (5,334,217).

Kazuyuki et al teaches:

108. (Currently Amended) A device for use in closing septal defects comprising:

a medial portion 3 (connecting member) having a longitudinal axis; and

first set of fingers 2 uncovered by a web;

and a closure member 1 having a web and frame 12. However, Kazuyuki et al is silent regarding the closure member being a second set of fingers, but does teach it can have varying shapes; see page 2, lines 10-15.

Das also teaches a septal defect device which has a closure member 22, 32 which can be many of the same shapes taught by Kazuyuki et al, however, further teaching



a star shape as shown in figure 5E. It would have been obvious to one having ordinary skill in the art to have made the closure member of Kazuyuki et al in a star shape as taught by Das as an operable substitution. Therefore, the frame of Kazuyuki et al would be formed of straight portions interpreted as arms which are capable of extending substantially radially outward from the axis.

Claim 111, see page 4, line 23 of Kazuyuki et al.

Claim 113, it would have been obvious to one having ordinary skill in the art have used/tried silicone for such a material for it's well known characteristics such as biocompatibility.

Claim 114, see figure 4.

Regarding at least claim 143 and 146, the fingers are made of wire which could have been formed from melting down the metal of a tube, sheet, anything.

Regarding claims 148-149, it would have been obvious to one skilled in the art to have made the implant form stainless steel or thermoplastic for their known use as cardiac device including septal defect devices, stents, etc. for their known characteristics including biocompatibility.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruce E Snow/  
Primary Examiner, Art Unit 3738